K061995

PHILIPS

Philips Medical Systems

SEP - 6 2006

510(k) Summary

Philips Xcelera

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

I General Information

Company Name:	Philips Medical Systems North America Company
Address:	22100 Bothell Everett Highway Bothell Washington 98021-8431 USA
Contact Person	Lynn T. Harmer
Telephone Number:	425-478-7312
Prepared (date):	2006 May 12
Manufacturing Site:	Philips Medical Systems Nederland B.V. Veenpluis 4-6 5684 PC Best, The Netherlands
Device Name:	Philips Xcelera
Classification Name:	Picture Archiving and Communication System
Regulation number	892.2050
Classification:	Class: II
ProCode:	90 LLZ
Common/Usual Name:	Workstation
Predicate Devices:	Philips Medical Systems, Harmony Siemens Medical Systems Inc., LEONARDO *syngo* Cardiology Workstation

II Information Supporting Substantial Equivalence Determination

System Description:

Philips Xcelera software is an integrated multimodality image and information system, designed to perform the necessary functions required for import /export/ storage / archiving / review / analysis/ quantification / reporting and database management of digital cardiovascular images, waveforms and data related to cardiology.
Xcelera offers support for third party plug-ins in order to enable the use of commercially available tools and for analysis, quantification and reporting Xcelera offers support to launch specified 3rd. party programs from the user interface (Desktop Integration).
It allows multiple users fast access to, and exchange of specific and/or multiple cardiology exams.

Philips Xcelera software runs on standard information technology hardware and software. The Xcelera proprietary software product utilizes the standard Microsoft Windows Operating System and user interface. Communication and data exchange are done using standard TCP/IP, DICOM and HL7 protocols.
Philips Xcelera will also be made available for use on specified Cardiovascular Monitoring Systems, which use suitable hardware components

The modular design allows configurability to tailor the image import, archive and communications solution to one's particular budgetary and performance needs. The number of modalities and reporting and/or viewing sites can be configured per system.

Intended Use:

Philips Xcelera software product is an integrated multimodality image and information system designed to perform the necessary functions required for import, export, storage, archival, review, analysis, quantification, reporting and database management of digital medical images.

General Safety and Effectiveness:

The Xcelera complies with ACR/NEMA DICOM digital imaging communication standard.

Conclusion:

The Philips Xcelera does not introduce new indications for use, nor does the use of the device result in any new potential hazard. Philips Medical Systems considers the Xcelera to be substantially equivalent to the Philips Medical Systems, Harmony (K022788) and the Siemens Medical Systems Inc., LEONARDO *syngo* Cardiology Workstation (K042203).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP - 6 2006

Philips Medical Systems North America
c/o Mr. Marc M. Mouser
Program Reviewer
Underwriters Laboratories, Inc.
2600 N. W. Lake Road
CAMAS WA 98607-8542

Re: K061995
Trade/Device Name: Philips Xcelera
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 4, 2006
Received: August 21, 2006

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(K) Number (if known): _____

Device Name: Philips Xcelera

Philips Xcelera software is an integrated multimodality image and information system, designed to perform the necessary functions required for import /export/ storage / archiving / review / analysis/ quantification (for example: area, circumference, volume, velocity, length, percent, time, ejection fraction, pressure gradient, LV volumes) / reporting and database management of digital cardiovascular images, waveforms and data related to cardiology.

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061995